## **REMARKS**

In the Office Action, the Examiner states that the Information Disclosure Statement does not comply with the requirements of 37 C.F.R. 1.98. In a telephone inquiry to the Examiner on March 12, 2003, reflected in the Inteview Summary Record, the Examiner said that the references were missing from the file. However, Applicants submitted the references with the Information Disclosure Statement on June 26, 2002, as evidenced by copies of the attached Certificate of Mailing and stamped postcard receipt dated July 2, 2002. For the Examiner's convenience, as requested, copies of the references are being resubmitted. Also attached hereto is a copy of the June 26, 2002 Supplemental Information Disclosure and PTO forms 1449. No fee is believed necessary because the Supplemental Information Disclosure Statement as originally filed was in compliance with the rules and was submitted before mailing of the first Office Action on the merits; the Patent Office error required resubmission of the references.

With respect to the objection to the drawings under 37 C.F. R. 1.83 (a), Figure 1 has been amended as shown in red on the attached sheet to illustrate the wire 22 with J-tip 24 extending from the catheter to better illustrate the wire within the catheter. A copy of the drawings incorporating the changes is also enclosed. No new matter has been added. The specification makes clear that the wire extends from the catheter. See e.g. page 6 lines 15-19 stating "A rotatable thrombectomy wire 22 preferably having a J-shaped tip designated generally 24 is slidably resident within major internal conduit 14. Wire 22 may be advanced out of a distal end 32 of major internal conduit 14 within catheter 12 to perform thrombectomy procedures...."; see also page 6, lines 22-24 stating "Connection ports 28,30 are preferably at the proximate end 34 of catheter 12, which is opposite distal end 32 of catheter from which wire 22 emerges to perform the thrombectomy procedure." Claim 5 has been canceled. Claim 18 has been canceled since its recitation of the first balloon being proximal of the second balloon is incorporated into claim 1. Applicants submit that this feature of balloon location is clearly shown in the drawings. For example, Figure 1 shows elongated balloon 18 proximal of spherical balloon 24. Claims 24 and 25 are therefore fully supported in the specification. Withdrawal of the objection to the drawings in light of the foregoing is respectfully requested.

With respect to the objection to the specification, amended Figure 1 shows the rotatable wire 22 with the J-tip extending from the catheter. Note that Figures 2 and 4 do not illustrate the rotatable wire since it is fully contained within the catheter and not yet advanced out of the distal end 32 of

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conduit 14 of the catheter. The objection is believed overcome. Also, a description of Figures 4 and 5 have been added. The reference numerals have been given prime designations to avoid confusion with the first embodiment. Attached corrected drawings of these Figures showing these changes in red is attached. A copy of the drawings incorporating these corrections is also submitted. No new matter has been added as the catheter as illustrated corresponds to the catheter of Figure 1 and clearly the lumen as illustrated is of a different configuration than Figure 2.

With respect to the rejection of claims 16-25 under 35 U.S.C. 112, second paragraph, claim 11 has been amended as shown above. Claims 16 and 19 have been canceled. The rejection should be withdrawn.

Claims 1,2,4-8 and 10-12 were rejected as anticipated under U.S. Patent No. 6,056,721 (Schulze). Claim 3 was rejected as anticipated or obvious over Schulze. Claims 15-25 were rejected over Schulze in view of U.S. Patent No. 5,766,192 (Zacca). The Schulze patent is directed to a catheter for drug treatment within the vascular conduit. The drug is injected in the region between the two inflated balloons, i.e. the sealed space between balloon 46 and balloon 40. In contrast, the present invention as defined in the amended independent claims recites that the balloons are proximal of the thrombectomy wire. Claim 1 recites the mechanical thrombectomy rotatable wire is distal of the balloons, and claims 10-12 recite that both balloons are proximal of the rotatable thrombectomy wire. Thus, these claims are not anticipated by Schulze. Claims 2 and 4-8 depend from claim 1 and are therefore patentable for at least the same reasons as claim 1.

Claim 3 is not rendered obvious since claim 3 depends from claim 1. It should also be noted that the Schulze patent does not teach or suggest placement of a mechanical thrombectomy device distal of the balloons. Schulze does not teach a mechanical thrombectomy device, i.e. a rotatable thrombectomy wire, but teaches fluid injection. The objective of Schulze is to improve fluid injection for thrombectomy. Furthermore, changing the location of the Schulze balloons relative to drug injection runs counter to the teachings and objectives of Schulze. The balloons of Schulze create a space for drug injection; moving the drug injection distal of the balloons would not enclose the drug treatment area but would do the opposite as flow would not be inhibited. Such arguments are also pertinent to the obviousness rejection of claim 15-25¹. Substituting a rotational member for the drug injection is counter to the teachings, objectives, and focus of the Schulze patent. Thus such combination is improper hindsight. Additionally, assuming solely for the sake of argument that the

 $<sup>^{1}</sup>$  Namely claims 17, 20, 24 and 25 since claims 15, 16, 18, 19 and 21-23 have been canceled.

rotational member of Zacca was substituted for drug injection, the requirements of the present invention would still not be met because the rotational member would be between the balloons and not distal of the balloons as required in claim 1 and its dependent claims 17, 20, 24 and 25. Thus, the obviousness rejection should be withdrawn.

Applicants respectfully submit that this application is now in condition for allowance. Prompt and favorable reconsideration of the present application is respectfully requested. The Examiner is invited to contact the undersigned should the Examiner believe it would expedite prosecution.

Respectfully submitted,

Dated:  $\frac{y}{\lambda} \frac{\lambda}{\delta} \lambda$ 

By:

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